

Appl. No. 10/577,887
Amdt. dated June 14, 2010
Reply to Office Action of March 16, 2010

Amendments to the Drawings:

The attached sheet of drawings includes changes to Fig. 3. This sheet, which includes Fig. 3, replaces the original sheet including Fig. 3. In Figure 3, reference number 27 is replaced with reference number 5, referring to cartilage. Reference number 29 is replaced with reference number 3, referring to bone.

Attachment: Replacement Sheet

REMARKS/ARGUMENTS

All pending claims are cancelled and replaced with new claims 20-28. The former claims were drawn to a bone site preparation device for removing damaged tissue from a bone site and for forming an annular groove around the site. The new claims are drawn to a method of using the device to prepare bone at a site for repair of damaged cartilage. The reamer, centralizing device, biasing means, cutting teeth, and debris channel previously recited in claim 7 are also set forth in the new claim 20. Support for claim 20 can be found in the specification as filed, referring to the published application paragraphs [0012], [0027] to [0029]. New claim 21 is based on original claim 9 as is supported specifically at paragraph [0029]. New claim 22 is based on original claim 10 and claims 23 to 28 are based on previously submitted claims 14 to 19.

Drawings

The Office objected to Figure 3 because reference number 29 is not described in the specification. Figure 3 was amended to address this objection. Withdrawal of the drawing objection is respectfully requested.

Claim Rejections – 35 USC § 103

The Office rejected claims 7, 10, and 14-19 under Section 103(a) as being unpatentable over the teachings of Scarborough et al. (U.S. Patent No. 5,928,238) in view of Spranza, III (U.S. Patent No. 6,884,245). The Office rejected claim 9 under Section 103(a) as being unpatentable over the teachings of Scarborough et al. in view of Spranza, III and further in view of Elias et al. (U.S. Patent No. 5,324,300). Even though the rejected claims have been cancelled, the merits of this rejection will be discussed below in relation to the pending claims.

The Scarborough, Spranza, and Elias patents disclose devices and methods of forming and removing bone plugs, cores, or dowels. While these patents individually disclose some of the features of the device used in the claimed method, none of the cited patents individually or in combination discloses or suggests the actual method of preparing bone at a site for the repair of damaged cartilage as recited in the pending claims.

Scarborough discloses a reamer 10 having a spring biased centralizer 44. Scarborough discloses a toothed cutting edge positioned about the centralizer 44. However, Scarborough does not disclose at least one debris channel extending from the cutting edge being additional and distinct from the cutting teeth by extending a greater distance along the reamer body with regard to the teeth.

Furthermore, Scarborough does not disclose a method of preparing of a bone site for the repair of damaged cartilage. In particular, the present method is directed to forming a narrow groove under very fine tolerances into the bone underlying the damaged cartilage. This groove is then used as a means to anchor a repair prosthetic at the cartilage layer, at the region where the damaged cartilage has been removed. For example, anchorage of a biocompatible pad is achieved via netting/mesh or tissue that is pushed and held in place by frictional contact within the narrow groove as detailed within the specification as filed paragraphs [0011] and [0013] of the published application and figures 1, 3 and 10. In contrast, Scarborough, like Elias, is directed to creating bone dowels by extracting the central bone column formed by the reamer.

As noted above, the reamer of Scarborough differs from the subject invention as it does not have a debris channel extending from the cutting edge of the reamer. The technical affect of the debris channel is to allow cut bone matter to pass from the interior of the reamer (defined by the circular zone of the cutting teeth and the reamer body) to a region outside of the cutting zone whilst the reamer is cutting. Primarily, the technical affect ensures that debris bone matter is transported away from the cutting zone as the cutting teeth are rotated. Without the debris channel the inventors have observed that at least some cut bone matter is retained in the groove. This debris matter within the groove is problematic as it provides an abrasive grinding affect on surrounding bone as the reamer is rotated to form the narrow groove. The result is a non-clean, low quality groove of non-uniform width and cross sectional profile along its length into the bone.

A consequence of the inaccurately formed groove and bone fragments present within the groove is to facilitate detachment of the bone column D, referring to figures 22 and 23 of Scarborough.

As detailed at paragraph [0039] of the subject application, it is important that groove 7 is cut to an accurate width such that the retaining sheet 11a is capable of firstly being inserted into

the groove and secondly to be anchored within the groove by frictional contact. This necessitates the groove is formed with a predetermined width. It is also important to ensure this width is created under very fine tolerances so as to ensure optimum initial mechanical anchorage prior to tissue ingrowth and the secondary biological fixation.

Frictional contact between the cylindrical walls of the reamer and the as-formed bone column due to the accumulation of bone fragments in the region of the groove is entirely unwanted with the subject invention as it is critically important that the surgical procedure does not detach the bone column. Moreover this detachment would result in complete failure of the present minimal invasive repair procedure. Scarborough therefore may be regarded as teaching away from the subject invention because it is directed to extracting dowels in contrast to a device for creating a narrow groove, and importantly, maintaining anchorage of the as-formed central bone column against which an implant is to be affixed.

Spranza discloses a bone coring cutter having a toothed cutting head 11. Three cutting teeth are formed in the cutting head referring to figure 2. Referring to figure 3, the trailing edge of each tooth is formed as a sharpened projection via a tooth clearance relief angle 18. Spranza does not disclose a reamer having a toothed cutting edge in addition to at least one debris channel that extend from the toothed region.

The cutter of Spranza differs significantly from the subject invention as the cutting edge is coned shaped so as to provide a 'dovetail' cross section referring to column 3, lines 56 to 64. This is designed to provide adequate clearance for the trailing shank. The cutter of Spranza is not designed to form a narrow groove into the bone and importantly does not comprise cutting teeth being distinct from debris channels. None of the objects stated in Spranza at column 2 relate to forming a narrow groove of predetermined width under very fine tolerances. Accordingly, the skilled person would find no motivation from Spranza to implement a toothed cutting edge in addition to at least one debris channel so as to ensure very accurate groove width creation. Spranza is directed to solving an entirely different problem and the skilled person would not be motivated or assisted to achieve the subject invention.

Elias discloses a device and method for controlled excision of bone cores. It was cited in the Office Action to disclose cylindrical cutter which can inter-fit with the reamer. Elias was combined with Scarborough and Spranza to reject claim 9 (comparable to new claim 21) which

is drawn to the use of a cartilage cutter at the repair site. A representative example of the claimed cartilage cutter is shown in Figure 5 of the specification. Even though Elias may disclose a cylindrical cutter, Elias fails to disclose the claimed method, including the method of claim 21 relating to forming the annular groove. Elias discloses a method that cuts and removes a bone core. Removing the bone core is expressly contrary to the claimed method.

In view of the foregoing, Applicants respectfully submit that claims 20-28 would not have been obvious from the combined teachings of Scarborough, Spranza, III, or Elias. Applicants respectfully request favorable consideration and allowance of claims 20-28. If there are any remaining issues preventing allowance of the pending claims that may be clarified by telephone, the Examiner is requested to call the undersigned.

Respectfully submitted,

/Evan R. Witt/

Evan R. Witt
Reg. No. 32,512
Attorney for Applicant(s)

Date: June 14, 2010
KIRTON & McCONKIE
1800 Eagle Gate Tower
60 East South Temple
Salt Lake City, Utah 84111
Telephone: 801/328-3600

The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-0843.
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